January 16, 2026

MY01 Inc.
Jennifer Robb
Director of Quality
400 Boulevard De Maisonneuve West
Suite 700
Montreal, QC H3A 1L4
Canada

Re: K251900
Trade/Device Name: MY01 Continuous Compartmental Pressure Monitor
Regulatory Class: Unclassified
Product Code: LXC
Dated: December 19, 2025
Received: December 19, 2025

Dear Jennifer Robb:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LIMIN SUN -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251900

Device Name
MY01 Continuous Compartmental Pressure Monitor

Indications for Use *(Describe)*
The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) Summary

The following information is submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: Dec 19th, 2025

807.92 (a)(1): SUBMITTER'S INFORMATION

Submitted by:	MY01, Inc. 400 De Maisonneuve Boulevard West, Suite 700 Montréal, Québec, H3A 1L4 Canada
Contact Person:	Jennifer Robb Director of Quality Tel: +1 (514)-261-2962 Email: jennifer.robb@my01.io
Establishment registration number:	3017398927
Owner Operator Number:	10061277

807.92 (a)(2): DEVICE INFORMATION

Device Trade Name:	MY01 Continuous Compartmental Pressure Monitor
Device Common Name:	Monitor, Pressure, Intracompartmental
Classification Name:	Unclassified
Classification Code:	LXC
Classification Panel	Orthopedic
Regulation Number:	Pre-Amendment, Unclassified

807.92 (a)(3): PREDICATE DEVICE

MY01 Continuous Compartmental Pressure Monitor, K242997 (MY01, Inc.)

807.92 (a)(4): DEVICE DESCRIPTION

The MY01 Continuous Compartmental Pressure Monitor (the MY01 device) allows for continuous measurement and real-time display of muscle compartment pressure that is intended to be used as an aid in the diagnosis of Compartment Syndrome (Acute and Chronic).

The MY01 device is a single-use, sterile, prescription medical device. It consists of two major components: the Introducer (with a plastic housing and 17-gauge stainless-steel needle that allows for placement of a pressure sensor into muscle compartments) and the Pressure Monitor. The Pressure Monitor is a battery-powered component controlled by integrated software and firmware. It utilizes a capacitive Micro-Electro-Mechanical System (MEMS) sensor embedded on a flexible printed circuit board (FPCB), which extends and connects via a lead-wire to a rigid

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PCB located within the device body that houses a liquid crystal display (LCD) and push-button to control device function. The sensor continuously outputs pressure values when inserted into the patient's muscle compartment. Muscle compartment pressure is measured relative to atmospheric pressure, which is captured by a secondary MEMS sensor embedded within the device body. The embedded software/firmware system in the Pressure Monitor handles all processing functions of the MY01 device. Pressure measurements, user notifications, and device status information are displayed on the LCD screen of the Pressure Monitor and stored in non-volatile memory.

The MY01 device communicates securely via Bluetooth with the MY01 Mobile Application (the MY01 App) to transmit and display continuously in real time the measured muscle compartment pressure, user notifications and device status information. The muscle compartment pressure is displayed on the MY01 App along with the estimated muscle perfusion pressure that is derived using a manually entered diastolic pressure. The perfusion pressure is calculated using a simple subtraction: Muscle Perfusion Pressure = Diastolic Pressure - Muscle Compartment Pressure. The muscle compartment pressure is displayed as real-time numerical values and a continuously updated graph to visualize pressure trends over time. The muscle perfusion pressure is also displayed continuously with a dashed black line, indicating the estimated perfusion pressure based on the latest diastolic pressure entry.

The MY01 App does not analyze or interpret pressure data and it does not control any function or the configuration of the MY01 device. The MY01 App is not intended for active patient monitoring.

Optionally, the MY01 App may connect via an encrypted Wi-Fi/Cellular network to the MY01 Application Server (a cloud-based server managed by MY01 Inc.) to transmit the recorded session and pressure data for off-line review, reporting and archival purposes. Registered clinicians using a MY01 device may review previously recorded session data on the MY01 App and may download this data from the cloud server as a comma separated value (.csv) file. The MY01 Application Server is a Non-Device Medical Device Data Systems (MDDS); it does not modify the device data, does not control the functions or parameters of any medical device, and does not analyze or interpret the device data.

Notable changes from the predicate device:

The device modifications that necessitated this 510(k) submission entail changes to the sensor assembly design for improved manufacturability. A new single-unit device dispenser box (secondary packaging) and a new single unit shipper box (tertiary packaging) have also been introduced.

807.92 (a)(5): INTENDED USE/ INDICATIONS FOR USE

The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.

The subject MY01 Continuous Compartmental Pressure Monitor has the same intended use and indications for use as the predicate device.

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807.92 (a)(6): TECHNOLOGICAL SIMILARITIES AND DIFFERENCES TO THE PREDICATE

Device Characteristic	Predicate Device (K242997)	Subject Device	Comparison
Manufacturer	MY01 Inc.	MY01 Inc.	Same
Device Trade Name	MY01 Continuous Compartmental Pressure Monitor	MY01 Continuous Compartmental Pressure Monitor	Same
Product Code	LXC – Monitor, Pressure, Intracompartmental	LXC – Monitor, Pressure, Intracompartmental	Same
Regulation	Pre-Amendment, Unclassified	Pre-Amendment, Unclassified	Same
Indications for Use	The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.	The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.	Same
Prescription Use	Yes	Yes	Same
Target Patient Population	Patients susceptible to developing compartment syndrome	Patients susceptible to developing compartment syndrome	Same
Intended Anatomical Site	Extremities	Extremities	Same
Clinical Environment of Use	Healthcare environment	Healthcare environment	Same
Means of Accessing Anatomical Site to Measure Pressure	Introducer consisting of plastic housing with attached 17-gauge stainless-steel needle	Introducer consisting of plastic housing with attached 17-gauge stainless-steel needle	Same
Pressure sensing technology	Capacitive Micro-Electro-Mechanical Sensor (MEMS)	Capacitive Micro-Electro-Mechanical Sensor (MEMS)	Same
Compartmental Pressure Display	Handheld LCD with adhesive strip backing for optional attachment to patient's skin	Handheld LCD with adhesive strip backing for optional attachment to patient's skin	Same

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Device Characteristic	Predicate Device (K242997)	Subject Device	Comparison
Pressure Range	-99.9 to 99.9 mmHg	-99.9 to 99.9 mmHg	Same
Sold Sterile	Yes	Yes	Same
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)	Same
Shelf Life	24 Months	24 Months	Same
Maximum Intended Duration of Use	18 hours	18 hours	Same
Power Source	Two non-rechargeable and non-replaceable 3V batteries	Two non-rechargeable and non-replaceable 3V batteries	Same
IP Rating (Ingress Protection)	IP52	IP52	Same
Wireless Connectivity	The monitor communicates securely via Bluetooth Low Energy (BLE) v4.2 with the MY01 Mobile Application	The monitor communicates securely via Bluetooth Low Energy (BLE) v4.2 with the MY01 Mobile Application	Same
EMC & Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2 FCC Subpart 15C	IEC 60601-1 IEC 60601-1-2 FCC Subpart 15C	Same
Firmware	v1.8.0	v1.8.0	Same
Pressure Sensor Assembly Design	The sensor assembly is encapsulated with epoxy and a biocompatible coating.	The sensor is encapsulated within a stainless steel cap and the same biocompatible coating.	Different This change does not adversely affect the device safety or effectiveness.
Device Packaging	The device packaging configuration comprises 2 dispensers, each containing 6 individually packaged sterile devices, in each shipper box.	The device packaging configuration comprises 1 single-unit dispenser, containing 1 individually packaged sterile device, in a single-unit shipper box.	Different. Changes were made to the dispenser (secondary packaging) and the shipper (tertiary packaging) to allow for more versatile single unit distribution. No adverse impact on package integrity or sterility.
MY01 Mobile Application	v1.22.0 iOS and Android Mobile device compatibility Access to cloud server via encrypted Wi-Fi or Cellular network connection for off-line review, reporting and archival purposes	v1.22.1 iOS and Android Mobile device compatibility Access to cloud server via encrypted Wi-Fi or Cellular network connection for off-line review, reporting and archival purposes	Different. The software has been updated with minor changes to GUI to clarify complementary information provided to trained healthcare professionals. The changes do not affect device function, safety or effectiveness.

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807.92 (b)(1), (b)(3): PERFORMANCE DATA

Distribution simulation (performed in accordance with ASTM D4169) and accelerated aging (in accordance with ASTM F1980) were conducted prior to comprehensive performance verification and validation testing. Sensor accuracy, reliability, mechanical integrity, chemical resistance, biocompatibility, and usability characteristics were successfully evaluated.

The integrity of the sterile barrier in the new single-unit shipping package configuration was also validated using FDA-recognized consensus standards.

The revised MY01 Mobile Application was successfully verified and validated as per IEC 62304 requirements.

Clinical testing was not required to demonstrate substantial equivalence for this device type.

807.92 (b)(1), (b)(3): SUBSTANTIAL EQUIVALENCE CONCLUSION

The changes to the sensor assembly design, the packaging of the MY01 Continuous Compartmental Pressure Monitor, and the MY01 Mobile Application do not raise new questions of safety and effectiveness. The evidence submitted in this 510(k) Notification supports a finding of substantial equivalence, as it demonstrates that the subject device fulfills its design and risk management requirements, it is as safe and as effective for its intended use, and it performs as well as or better than the legally marketed predicate device.